



DIVISION OF  
CORPORATION FINANCE

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

May 22, 2018

Ashleigh Palmer  
President & Chief Executive Officer  
Provention Bio, Inc.  
110 Old Driftway Lane  
Lebanon, New Jersey 08833

**Re: Provention Bio, Inc.**  
**Form S-1**  
**Filed on May 9, 2018**  
**Amendment 1 to Form S-1**  
**Filed on May 16, 2018**  
**File No. 333-224801**

Dear Mr. Palmer:

We have reviewed your registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by amending your registration statement and providing the requested information. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

Form S-1 Filed May 9, 2018

Prospectus Summary, page 1

1. We note your response to comment 4 and continue to object to the characterization of your licenses as partnerships. A partnership implies a sharing of revenues and development expenses or a development cooperative effort .
2. Please clarify the distinction between "proof of mechanism" and efficacy.

PRV-031 (Teplizumab; anti-CD3 antibody) for T1D, page 3

3. Please delete the statement that you believe the PROTECT study will have a relatively high probability of success. It is not appropriate to predict the outcome of the clinical trial.

PRV-6527 (Small Molecule CSF-1R Inhibitor) for Crohn's Disease, page 4

4. With respect to your statement that "no safety signals were observed," please clarify if this means there were no serious adverse events. If it does not, please clarify whether there were any serious adverse events and clarify what safety signals the parties conducting the trials were monitoring for. Similarly revise other statements relating to safety signals throughout your document.

PRV-3279 (humanized CD32B x CD 79B Dual Affinity Re-Targeting (DART) biologic) for SLE and other autoimmune diseases, page 6

5. We note your statement that PRV-3279 has been studied in humans in a Phase 1a single ascending dose study in healthy volunteers and was observed to have no impact on efficacy. Please identify the target indication of the initial trial.

We are a virtual biopharmaceutical company with a limited history., page 12

6. We note your response to comment 6, including your stated belief that you have the proper security and controls in place to protect your confidential information. Your statement appears to indicate that you believe your security and controls remove all reasonable risks that your systems or those of third party service providers could be hacked or that a third party could gain unauthorized access to any of your confidential information. We continue to believe that the virtual nature of your operations continue to present a risk that warrants a risk factor discussion.

Business, page 48

7. Please revise the subheadings referencing "safety" to clarify there has been no safety determination. See "Clinical Safety of PRV-6527" "Safety, Pharmacology and Proof of Mechanism for PRV-300," Clinical Safety of PRV-300," "Pre-clinical Safety of PRV-300," "Clinical Safety of PRV-031," etc. Similarly, revise statements referencing the "clinical safety data." You may reference tolerance or the absence of serious adverse effects but the current disclosure appears to indicate there have been determinations regarding the safety of the product candidates.
8. Similarly, revise the headings referencing efficacy of your product candidates. You may reference Clinical Trials or results but the current presentation may imply the trials support an efficacy determination.

Clinical Safety of PRV-031, page 68

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9. We note your disclosure that "[t]here were no major differences in the overall adverse events and serious adverse event between PRV-031 and placebo." Please revise to provide the following information: what adverse events were reported with placebo; the number of patients who have experienced an adverse event; and whether any such events were characterized as severe.

Macrogeneics Agreements, page 75

10. Please revise to quantify the third party obligation that you are obligated to pay. Additionally, provide an analysis supporting your determination that you are not required to file the agreement as an exhibit.

Item 15. Recent Sales of Unregistered Securities, page 116

11. Please revise your disclosure to identify the person or class of persons who purchased the securities in each sale. Please note that an accredited investor, employee and consultant is an appropriate class of persons, but founders and partners are not.

We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

Refer to Rules 460 and 461 regarding requests for acceleration. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

You may contact Keira Nakada at 202-551-3659 or Angela Connell at 202-551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Jeffrey Gabor at 202-551-2544 or Suzanne Hayes at 202-551-3675 with any other questions.

Division of Corporation Finance  
Office of Healthcare & Insurance

cc: Michael J. Lerner